

## REMARKS

It is respectfully submitted that the present response presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the following remarks is requested.

### I. Status of Application

Applicants acknowledge with appreciation that the Examiner has entered the request for continued examination and submission filed on 11/08/2010.

### II. The Rejection of Claims 6, 8, 10, 13 under 35 U.S.C. 103(a)

Claims 6, 8, 10 and 13 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Roggen, US 2003/144165 ("R1") in view of Pomeranz et al., J. Am. Oil Chem. Soc., 43:45-48 (1966) ("R2") and Ghannoum, Clinical Microbiol. Rev., 13:122-143 (2000) ("R3"). The Examiner alleges that R1 discloses testing lipolytic enzymes for a specific activity, selecting lipolytic activities toward phospholipases, specifically the phospholipases which specifically hydrolyze digalactosyl diglycerides, and adding such enzymes to a dough for making bread. The Examiner states that R2 discloses the polar lipids of wheat flour, so that *any* of the phospholipids would be obviously selected for hydrolysis. The Examiner states that R3 discloses how to assay for phospholipase B by the plate method. The Examiner contends that it would have been obvious to one of ordinary skill in the art to test either natural lipolytic enzymes or variants thereof for a specific activity, select the lipolytic enzyme of interest, and add it to the dough for bread baking.

The Examiner also states that Applicants' prior arguments have been considered but are moot in light of the new grounds of rejection.

This rejection is respectfully traversed.

Applicants' claims are directed to a method of selecting a lipolytic enzyme for use as a baking additive comprising incubating at least one lipolytic enzyme with N-acyl phosphatidyl ethanolamine (APE) or N-acyl lysophosphatidyl ethanolamine (ALPE), b) detecting hydrolysis of an ester bond in the APE or ALPE, c) incubating the at least one lipolytic enzyme with phosphatidyl choline (PC), d) detecting hydrolysis of an ester bond in the PC, and e) selecting a lipolytic enzyme which has a higher hydrolytic activity on the ester bond in the APE or ALPE than on the ester bond in the PC.

Obviousness is a question of law based on underlying findings of fact. An analysis of obviousness must be based on several factual inquiries: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the

art at the time the invention was made; and (4) objective evidence of nonobviousness, if any. *Graham v. John Deere Co.*, 148 USPQ 459, 467 (1966). The teachings of a prior art reference are underlying factual questions in the obviousness inquiry. *Para-Ordnance Mfg., Inc. v. SGS Imp. Int'l, Inc.*, 37 USPQ2d 1237, 1240 (Fed. Cir. 1995). “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007) (quoting *In re Kahn*, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)).

Appropriate rationales for obviousness in accordance with *KSR* and the USPTO guidelines include:

1. Combining prior art elements according to known methods to yield predictable results
2. Simple substitution of one known element for another to obtain predictable results
3. Use of a known technique to improve similar devices (methods or products) in the same way
4. Applying a known technique to a known device (method or product) ready for improvement to yield predictable results
5. “Obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success
6. Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predicable to one of ordinary skill in the art
7. Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art teachings to arrive at the claimed invention

See *Federal Register* / Vol. 72, No. 195 / Wednesday, October 10, 2007 / Notices. See also MPEP 2141.

Moreover, “[a] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR*, 82 USPQ2d at 1389. To find obviousness, the Examiner must “identify a reason that would have prompted a person of ordinary skill in the art in the relevant field to combine the elements as the new invention does. Inventions usually rely upon building blocks long since uncovered, and claimed discoveries almost necessarily will be combinations of what, in some sense, is already known.” *Id.* 35 U.S.C. 103(a) bars patentability unless “the improvement is more than the predictable use of prior art elements according to their established functions.” *Id.* at 1396. An

impermissible "obvious to try" situation occurs where what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988).

In this case, the Examiner failed to provide a clear and appropriate rationale for obviousness. For example, it is unclear with the Examiner is applying the obvious-to-try rationale (number 5) by discussing that *any* of the phospholipids would be obviously selected for hydrolysis. It is important that the rationale be clear in this case, because the prior art cited by the Examiner does not include the specifically-claimed method steps. Applicants respectfully submit that it appears that a combination of rationales is offered in an attempt to fill the deficiency that each and every element of the claimed invention has not been shown in the prior art references. Here, the Examiner has admitted that the cited references do not specifically disclose the specifically-claimed method steps. Absent a clear rationale, the Examiner has failed to make a *prima facie* case of obviousness.

Even assuming arguendo that the Examiner is applying an "obvious to try" rationale for the obviousness allegation (which Applicants' do not concede to be clear), Applicants respectfully submit that the Examiner's contentions must fail.

The Examiner appears to contend that it would have been obvious to one of ordinary skill in the art to test *any* natural lipolytic enzymes or variants thereof for *any* specific activity, select the lipolytic enzyme of interest, and add it to the dough for bread baking. Moreover, the Examiner contends that *any* of the naturally-occurring phospholipids of wheat flour disclosed in R2 would be obviously selected for hydrolysis.

In so doing, the Examiner appears to simply ignore the particular elements of Applicants' claims and instead comes to a cursory conclusion that the claims are obvious.

In particular, the pending claims require not only hydrolysis of an ester bond of particular phospholipids (namely, APE or ALPE as in step b) and PC as in step d)), but critically, the claims require *selecting a lipolytic enzyme which has a higher hydrolytic activity on the ester bond in the APE or ALPE than on the ester bond in the PC*. It is the critical selection step e) which the art cited by the Examiner fails to appreciate.

As stated in the prior response, Applicants do not dispute that phospholipases were known in the art as bread improvers as of the priority date of the present invention. In fact, it was the desire to rapidly screen *other* lipolytic enzymes to identify candidates for a baking additive which can improve the properties of a baked product when added to the dough which is the subject of the present invention. See, page 1, lines 20-22.

Applicants also do not dispute that various phospholipids were known in the art to be naturally occurring in wheat. Page 1, lines 15-18. In fact, it is the ability to distinguish among the activities among these particular substrates which is the subject of the present invention. See page 3, lines 12-18.

As set forth in the specification as filed, evaluation of full-scale baking tests generally requires a major effort for isolating and producing each enzyme in sufficient quantity. Page 1, lines 9-11. In contrast to what was known in the art, the present inventors have developed a method of screening lipolytic enzymes to identify candidates for a baking additive which can improve the properties of a baked product when added to the dough. Page 1, lines 20-22. Lipolytic enzyme candidates selected according to the claimed screening methods can then be used in full-scale baking tests for further evaluation. Page 1, lines 9-11.

Nowhere does R1 teach or suggest the screening methods of Applicants' claims, and in particular, nowhere does R1 teach or suggest the *selection of a lipolytic enzyme which has a higher hydrolytic activity on ester bonds in the APE or ALPE than on ester bonds in the PC*.

Neither does R2 or R3 teach or suggest the claimed screening methods. Nowhere do R2 or R3 teach or suggest the *selection of a lipolytic enzyme which has a higher hydrolytic activity on ester bonds in the APE or ALPE than on ester bonds in the PC*.

Thus, neither R1 nor R2 and/or R3, either alone or in combination, teach or suggest Applicants' claimed methods.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103(a). Applicants respectfully request reconsideration and withdrawal of the rejection.

### **III. Conclusion**

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

All required fees were charged to Novozymes North America, Inc.'s Deposit Account No. 50-1701 at the time of electronic filing. The USPTO is authorized to charge this Deposit Account should any additional fees be due.

Respectfully submitted,

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